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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/565,058

06/21/2006

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002.00270

2111

35876 7590 02/25/2009  
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EXAMINER

SWOPE, SHERIDAN

ART UNIT

PAPER NUMBER

1652

MAIL DATE

DELIVERY MODE

02/25/2009

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/565,058	<b>Applicant(s)</b> HARDIE ET AL.	
	<b>Examiner</b> SHERIDAN SWOPE	<b>Art Unit</b> 1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 28 November 2008.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-12, 14, 16, 19-29 and 31-35 is/are pending in the application.
- 4a) Of the above claim(s) 1, 2, 6-12, 14, 21-29 and 31-35 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 3-5, 16, 19, and 20 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

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**DETAILED ACTION**

Applicants' amendment of November 28, 2008, in their response to the action of May 19, 2008 is acknowledged. It is acknowledged that no claims have been cancelled, amended, or added. Claims 1-12, 14, 16, 19-29, and 31-35 are pending. Claims 1, 2, 7-12, 14, 21-29, and 31-35 were previously withdrawn from further consideration pursuant to 37 CFR 1.142(b). Claim 6 is herein withdrawn from further consideration pursuant to 37 CFR 1.142(b). Claims 3-5, 16, 19, and 20 are hereby reexamined.

***Claim Rejections - 35 USC § 112-Second Paragraph***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Rejection of Claims 3-5, 16, 19, and 20, because the phrase "A purified preparation comprising LKB1, STRAD, and recombinant MO25" renders the claim indefinite, is maintained. In support of their request that said rejection be withdrawn, Applicants argue that one skilled in the art would have understood the metes and bounds of the recited invention in view of the specification's teaching (pg 23, lines 24- 27).

This argument is not found to be persuasive for the following reasons. It is acknowledged that the specification (pg 23, lines 24- 27) states:

By "purified" is meant that the preparation has been at least partially separated from other components in the presence of which it has been formed, for example other components of a recombinant cell.

However, said statement does not provide a definition of the metes and bounds of the recited invention. For example, the specification also states the following.

"The preparation may be substantially pure. By "substantially pure" we mean that the said polypeptide(s) are substantially free of other proteins. Thus, we include any composition that

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includes at least 30% of the protein content by weight as the said polypeptides, preferably at least 50%, more preferably at least 70%, still more preferably at least 90% and most preferably at least 95% of the protein content is the said polypeptides.” (pg 24, lines 1-6)

The skilled artisan would not know if a “purified” preparation is encompassed by a “substantially pure” preparation, is less pure than a “substantially pure” preparation, or is more pure than a “substantially pure” preparation. For purposes of examination, it is assumed that “A purified preparation comprising LKB1, STRAD, and recombinant MO25” means any non-cellular composition comprising LKB1, STRAD, and recombinant MO25.

Rejection of Claim 19, because recitation of “identifying a compound for modulating cellular LKB1 activity...a preparation according to claim 3” renders the claim indefinite, is maintained. In support of their request that said rejection be withdrawn, Applicants provide the following arguments. The use of the word “cellular” is in the preamble. Thus, the method of claim 19 is for identifying a compound that modulates cellular LKBI activity (i.e., a compound that modulates LKBI activity in a cell). The remainder of the claim sets out the method by which such a compound is to be identified. The method for identifying such a compound is carried out with a purified (e.g., a non-cellular) preparation of claim 3. The facts (i) that the method for identifying a compound may be carried out in vitro and (ii) that the compound, once identified, may be capable of modulating cellular (i.e., in vivo) LKBI activity does not render the claim indefinite.

These arguments are not found to be persuasive for the following reasons. It is acknowledged that use of the word cellular is in the preamble. Thus, the identified compounds must be effective at modulating LKB1 activity in a cellular context. The claim recites no steps to test whether or not a compounds is effective at modulating LKB1 activity in a cellular context.

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Moreover, the skilled artisan would know that many compounds effective in vitro, including some peptides, would not be effective in vivo because they cannot pass the plasma membrane.

Rejection of Claims 19 and 20 as being indefinite because “a preparation according to Claim 3” should be corrected to “the preparation according to Claim 3”, is maintained. See MPEP 2173.05(f).

Rejection of Claim 20, because “the substrate” lacks antecedent basis, is maintained. See MPEP 2173.05(e).

***Claim Rejections - 35 USC § 112-First Paragraph***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

**Enablement**

Rejection of Claims 3-5, 16, 19, and 20 under 35 U.S.C. 112, first paragraph/ lack of enablement, for the reasons explained in the prior action, is maintained. In support of their request that said rejection be withdrawn, Applicants provide the following arguments.

(A) With regard to LKBI, the specification discusses at page 12, line 22 to page 14, line 2, what is encompassed by “LKBI”.

(B) With regards to STRAD and MO25, the specification teaches examples via citations and accession numbers (pg 14, line 4, to pg 15, line 8).

These arguments are not found to be persuasive for the following reasons.

(A) Reply: It appears that this argument is more relevant to rejection under 35 USC 112, second paragraph. Nonetheless, the following comments are made. As explained in the

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prior actions and acknowledged by Applicants, the term “LKB1” encompasses any protein, having any structure (any “variant”) and any fragment thereof, and having some “ability to phosphorylate or activate AMPK” (parg brdg pg 12-13). It is acknowledged that the specification discloses the LKB1 proteins disclosed by gi/3063585, gi/3024670, and gi/4507271. However, said disclosure does not enable the skilled artisan to make and used any variant of gi/3063585, gi/3024670, gi/4507271, or any other LKB1 protein having some ability to phosphorylate or activate AMPK. Neither the specification nor the prior art disclose the motifs and amino acid residues that may or may not be altered and still retain the desired activity, or how any motifs and amino acid residues may be altered and still retain the desired activity. The specification fails to enable the skilled artisan to make and use the full scope of said proteins without undue experimentation.

(B) Reply: As explained in the prior actions and acknowledged by Applicants, the term “STRAD” encompasses any protein, having any structure (any “variant”) and any fragment thereof, having some ability “to bind to the MOS25 and to LKB1”, while the term “MO25” encompasses any protein, having any structure (any “variant”) and any fragment thereof, having some ability “to bind to the STRAD or complex of LKB1 and STRAD” (pg 14 parg 2). Again, neither the specification nor the prior act disclose the motifs and amino acid residues that may or may not be altered and still retain the desired activity, or how any motifs and amino acid residues may be altered and still retain the desired activity. The specification fails to enable the skilled artisan to make and use the full scope of the recited proteins without undue experimentation.

For these reasons and those explained in the prior action, rejection of Claims 3-5, 16, 19, and 20 under 35 U.S.C. 112, first paragraph/lack of enablement, is maintained.

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### **Written Description**

Rejection of Claims 3-6, 16, 19, and 20 under 35 U.S.C. 112, first paragraph/written description, for the reasons explained in the prior action, is maintained. In support of their request that said rejection be withdrawn, Applicants argue that the rejection is based on an assertion that the specification fails to disclose the exact structural identity of any STRAD or MO25 protein.

These arguments are not found to be persuasive for the following reasons. It is acknowledged that the specification teaches examples of LKB1, STRAD, and MO25 proteins. However, the specification fails to disclose the genus of any “purified preparation” comprising any LKB1, STRAD, and MO25 proteins, having any structure, as encompassed by the instant claims, such that the skilled artisan would recognize that Applicants were in possession of the invention at the time of filing..

For these reasons and those explained in the prior action, rejection of Claims 3-5, 16, 19, and 20 under 35 U.S.C. 112, first paragraph/written description, is maintained.

### ***Allowable Subject Matter***

No claims are allowable

Applicant's amendment necessitated any new grounds of rejection presented in this Office action. Any new references were cited solely to support rejection(s) based on amendment or rebut Applicants' arguments. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Regarding filing an Appeal, Applicants are referred to the Official Gazette Notice published July 12, 2005 describing the Pre-Appeal Brief Review Program.

#### **Final Comments**

To insure that each document is properly filed in the electronic file wrapper, it is requested that each of amendments to the specification, amendments to the claims, Applicants' remarks, requests for extension of time, and any other distinct papers be submitted on separate pages.

It is also requested that Applicants identify support, within the original application, for any amendments to the claims and specification.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sheridan L. Swope whose telephone number is 571-272-0943.

The examiner can normally be reached on M-F; 9:30-7 EST.



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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Nashed can be reached on 571-272-092834. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published application may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on the access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/SHERIDAN SWOPE/  
Primary Examiner, Art Unit 1652